UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/531,818	06/01/2006	Ghaleb Slater	PA1906 US2	3928

28390 7590 11/14/2007

MEDTRONIC VASCULAR, INC.
IP LEGAL DEPARTMENT
3576 UNOCAL PLACE
SANTA ROSA, CA 95403

EXAMINER	
RICE, BENJAMIN P	

ART UNIT	PAPER NUMBER
4175	

NOTIFICATION DATE	DELIVERY MODE
11/14/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

rs.vasciplegal@medtronic.com

Office Action Summary	Application No.	Applicant(s)	
	10/531,818	SLATER, GHALEB	
	Examiner	Art Unit	
	Benjamin P. Rice	4175	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *10-16* is/are allowed.

6)☒ Claim(s) *1-7* is/are rejected.

7)☒ Claim(s) *8 and 9* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *18 April 2005* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *06/23/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Drawings

1. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: 180, Fig. 5 (appears to be reference 170). Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-3 and 5-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Cunci et al. (US 5,752,969).

With respect to claim 1, Cunci et al. discloses a device for treating cardiac valve regurgitation (device as shown in Fig. 8-10 is capable of being used to treat a cardiac valve regurgitation), comprising: a tube including a lumen there through (tube 23, Fig. 10); a compression member carried on the tube (spring blade 26, Fig. 10); and a sleeve rotatably disposed about the tube and the compression member (tube 22, Fig. 9), the sleeve including a side port formed therein (opening 24, Fig. 9), wherein the side port is alignable with the compression member by relative rotation between the sleeve and the compression member (Column 6, Lines 23-30, also shown in Fig. 8).

With respect to claim 2, Cunci et al. discloses that the compression member has a pre-shaped compression configuration that is distendable outwardly through the side port (Column 6, Lines 17-30 explain that it distends outwardly and that the relaxed configuration (considered the preshaped configuration) is when it is distended).

With respect to claim 3, Cunci et al. discloses that the compression member is a spring, as it is a spring blade.

With respect to claim 5, Cunci et al. discloses that when the compression member distends outwardly through the side port (explained above with respect to claim 2), the compression member is capable of abutment against an interior wall of a blood vessel (since the device is a implantable tube, it is capable of being placed within a blood vessel, and since the spring blade is distendable from the side opening, it is capable of abutment against the wall of a blood vessel).

With respect to claim 6, Cunci et al. discloses that the abutment of the compression member against an interior wall of a blood vessel applies a compressive

force to the cardiac valve (This is considered intended use. It is well known in the art that if the implant is implanted into the coronary sinus and provides a compressive force near where it coincides with the mitral valve, it will apply a compressive force to the mitral valve. For an example of this commonly known aspect, see Background information in US 6,793,673 to Kowalsky et al. Since this device is capable of being implanted in the coronary sinus vessel, and also applies an outward force by the spring blade when the tube is against another surface, it is capable of applying the force to the coronary sinus which would compress the mitral valve).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cunci et al. (US 5,752,969) in view of Stephens et al. (US 4,604,995)

With respect to claim 4, Cunci et al. does not specifically disclose that the compression member is made of a material as listed in claim 4. However, Cunci et al. does disclose that most of the parts in the device are made of metal (Column 4, line 45). Stephens et al. also disclose that a medical implant for insertion into the body can be made of stainless steel (Column 2, lines 58-59). Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the compression member to be made of stainless steel, as one of ordinary skill in the art would recognize that it is a long time practice and well known in the art to use stainless steel as well as other metals for the use in various medical implants.

7. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kowalsky et al. (US 6,793,673) in view of Cunci et al. (US 5,752,969).

With respect to claim 7, Kowalsky et al. discloses a device for treating cardiac valve regurgitation (Column 2, Lines 18-20), comprising: a tube (device 70, Fig. 9); a compression member carried on the tube (96 and 78, Fig. 10); and a sleeve rotatably disposed about the tube and the compression member (locking member 98, Fig. 9). Kowalsky et al. also discloses a delivery catheter (92, Fig. 8 & 9), and a release mechanism to releasably attach the delivery catheter to the treatment device (since there is no structural limitation on the release mechanism, the operator could be considered the mechanism to releasably attach the two together, as he could move the device into and through the catheter).

However, Kowalsky et al. does not disclose that the tube includes a lumen there through. However, Cunci et al. discloses a tube with a compression member on the

outside of the tube with a lumen (Fig. 10, part 26). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device to have the compression member on a lumen in view of the teaching of Cunci et al., as one of ordinary skill in the art would recognize that it would be desirable to allow blood or other bodily fluids to pass while providing compression against the coronary sinus wall, as to minimally disrupt bodily function.

Kowalsky et al. also does not disclose that the sleeve includes a side port formed therein, wherein the side port is alignable with the compression member by relative rotation between the sleeve and the compression member. However, Cunci et al. discloses a sleeve (part 22, Fig. 8) with a side port (part 24, Fig. 8) that is alignable with a compression member by relative rotation between the sleeve and compression member (as seen in Fig 8 with a compression member 26). It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the sleeve of Kowalsky et al. to the sleeve of Cunci et al. in view of the teaching of Cunci et al., as Cunci et al. discloses a different mechanism of releasing the compression member than Kowalsky et al., and since the major difference between the two sleeves is their mechanism of releasing the compression member (Kowalsky et al. retracts the sleeve to release the member, Cunci et al. releases the member through the side port), it is considered a mechanical equivalent as they both provide the same function of releasing the compression member. A change between mechanical equivalents is considered within the level of one of ordinary skill in the art.

Allowable Subject Matter

8. Claims 8-9 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

9. The following is a statement of reasons for the indication of allowable subject matter: With respect to claims 8 and 9, while the prior art shows all the limitations with respect to claim 7, the prior art does not disclose or render obvious a system that has a device as explained with respect to claim 7 along with a catheter that has either a threaded release mechanism or a driving catheter with a keyway for receiving the compression member. Such an addition of those mechanisms can not be considered obvious with respect to different prior art references as it would change how the catheter functions and would teach away from how the device is implanted with respect to the base reference by Kawalsky et al.

10. Claims 10-16 are allowed.

11. The following is a statement of reasons for the indication of allowable subject matter: With respect to claim 10, the prior art shows the structural limitations of the device as claimed, however the prior art does not disclose or render obvious applying the method in the prior art to a blood vessel and rotating the sleeve to deploy the member from a opening in the sleeve to contact a blood vessel. While the prior art devices are capable of such a method, and there is prior art that does disclose a method for compressing a blood vessel, those devices do not use the rotation of the sleeve to have a member go through an opening in the sleeve. Furthermore, the prior

art device that meets the structural limitations has a method that is not for cardiac procedures, thus not rendering it obvious to apply the art to the cardiac methods.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Benjamin P. Rice whose telephone number is (571) 270-3507. The examiner can normally be reached on Monday - Thursday 7:30am-5:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terrence Till can be reached on (571) 272-1280. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/BR/

/Terrence R Till/
Supervisory Patent Examiner, Art Unit 4175